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Remarks/Arguments

In the Final Office Action dated 7/22/2005, the pending claims were rejected for the following reasons:

Claim 1: The claim was rejected because it contained nonelected subject matter.

Claims 15-22: The rejection was maintained under 35 USC 112, second paragraph, stating that the claims were indefinite and failed to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 4, and 12-32: The rejection was maintained under 35 USC 112, first paragraph, stating that the claims failed to comply with the enablement requirement.

Claim 1 & Nonelected Subject Matter

Claim 1 has been amended to remove nonelected subject matter. Applicants respectfully request that this rejection be reconsidered and withdrawn.

Claims 15-22 Rejected Under 35 USC 112, Second Paragraph

Applicants respectfully disagree with the rejection of claims 15-22 under 35 USC 112, second paragraph. However, to facilitate prosecution of this matter, Applicants have amended claims 13, 15, and 16 and have cancelled the other claims that have been rejected. Applicants reserve the right to file a subsequent application covering the cancelled subject matter. Applicants respectfully request that this rejection be reconsidered and withdrawn.

Claims 1, 3, 4, and 12-32 Rejected Under 35 USC 112, First Paragraph

Said claims have been amended to facilitate prosecution. Applicants disagree that they are not enabled but make said amendments to facilitate prosecution. Applicants reserve the right to file a subsequent application covering the cancelled subject matter. Applicants further provide traverse in support of allowance of the claims as amended. Applicants respectfully request that this rejection be reconsidered and withdrawn.

The test for enablement is whether the experimentation needed to practice the invention is undue or unreasonable. *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited - Charge Cell Culture Microcarriers*, 221 U.S.P.Q. 1165, 1174 (Int'l Trade Comm) 1983),

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Aff'd. sub. nom., Massachusetts Institute of Technology v. A.Z.B. Fortia, 774 F.2d 1104, 227 U.S.P.Q. 428 (Fed. Cir. 1985). Nothing more than objective enablement is required, and therefore, it is irrelevant whether the teaching is provided through broad terminology or illustrative examples. *In re Wright*, 000 F.2d 1557, 1561 (Fed. Cir. 1993); *In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971). In *In re Brana*, 51 F.3d 1560 34 USPQ2d 1436 at 1441 (1995), the court stated:

[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

In re Marzocchi, 58 C.C.P.A. 1069, 439 F.2d 220, 223, 169 U.S.P.Q. (BNA) 367, 369 (CCPA 1971). From this it follows that the PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. *Id.* at 224, 169 U.S.P.Q. (BNA) at 370. Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility. See *In re Bundy*, 642 F.2d 430, 433, 209 U.S.P.Q. (BNA) 48, 51 (CCPA 1981). [Emphasis in original. Footnote omitted.]

Applicant is not required to provide clinical data as if applying to the FDA for approval of a drug candidate; by providing the data and how to make the compounds of the claimed invention (please see US 2004/0029876 A1, page 10, paragraph 0128 to page 12, paragraph 0141 in addition to the complete detailed description), Applicants believe that the enablement requirement has been satisfied:

Usefulness in patent law, and in particular in context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were [the court] to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer. [*Brana*, at 1442-1443.]

Applicants respectfully request that this rejection be reconsidered and withdrawn.

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Amendments

Amendments to claim 1 were to remove nonelected subject matter. Furthermore, a semicolon was placed at the end of the definition of R³ and R⁴ due to part of the definition being deleted. Moreover, the parenthetical within the definition of, R¹⁰, R¹¹, R¹², R¹³, R¹⁴, R¹⁶, R¹⁷, R¹⁸ and R¹⁹ was stricken.

Support for amended claim 13 can be found at least on page 4, paragraph 0052 to page 5, paragraph 0087 of US 2004/0029876 A1.

Support for new claim 33 can be found at least in Examples 1 and 3 on page 11, paragraph 0130 to page 12, paragraph 0139 of US 2004/0029876 A1.

Support for amended claim 15 can be found at least on page 2, paragraph 0026 of US 2004/0029876 A1.

Support for amended claim 16 can be found at least in paragraph 0027 beginning on page 2, spanning to page 3 of US 2004/0029876 A1.

Applicants specifically reserve the right to file any subsequent patent application on the cancelled subject matter and nonelected subject matter.

Conclusion

Applicants believe that the claims are in order for allowance, early notice of which is requested. If Examiner has any questions concerning this application, Examiner is invited to contact the below-signed attorney. It is believed that no fee due. However, if there is a fee due, please charge any payment or credit any overpayment to Charge Account 16-1445.

Respectfully submitted,



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